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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,826	08/13/2002	Mark J. Pykett	C01005/70008	5264

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,826

Applicant(s)

PYKETT ET AL.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,9-16,18-20 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,9-16,18-20 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 05/03/06 is acknowledged.
2. Claims 1, 2, 5, 9-16, 18-20, 24-29 are pending.
3. *Claims 1, 2, 5, 9-16, 18-20, 24-29 reads on a method for in vitro culture of hematopoietic progenitor cells to produce differentiated cells, wherein differentiated cells are neuronal cells and wherein growth factors are bFGF and EGF and wherein solid matrix is tantalum-coated are under consideration in the instant application.*

In view of the amendment, filed 05/03/06 the following rejection remains

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 5, 9-16, 18-20, 24-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/15629 in view of the known fact disclosed in the Specification on page 11, lines 9-26 and US Patent 6,830,927 for the same reasons set forth in the previous Office Action, mailed on 12/30/05.

Applicant's arguments, filed 05/03/06 have been fully considered, but have not been found convincing

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Applicant asserts that: (i) WO'629 teaches an *in vitro* method of culturing hematopoietic progenitor cells in their pluripotent state. However, WO'629 does not disclose a method of culturing progenitor cells in the environment that promote differentiation to produce neuronal cells; (ii) US Patent '927 teaches a method for *in vitro* culturing neuroepithelial stem cells to produce nervous system lineages. However, US Patent' 629 does not contemplate that its progenitor are able to differentiate into any lineages other than hematopoietic lineages; (iii) there is no motivation or suggestion to combine the cited references at least because the references teach different progenitor populations.

Applicants have traversed the primary and the secondary references pointing to the differences between the claims and the disclosure in each reference. Applicant is respectfully reminded that the rejection is under 35 USC103 and that unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references. see *In re Keller*, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981) See MPEP 2145. This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. *In re Young* 403 F.2d 759, 150 USPQ 725 (CCPA 1968).

On page 6 of Applicant's arguments, filed 05/03/06, Applicant acknowledge that US Patent '927 teaches that its progenitor differentiate into nervous system lineages. The Examiner requests clarification how said statement correlates with Applicant's assertion that "US Patent '927 does not contemplate that its progenitor are able to differentiate into any lineages other than hematopoietic lineages.

With regards to the statement that "there is no motivation or suggestion to combine the cited references at least because the references teach different progenitor populations.

The Examiner disagrees with said statement. At issue is not whether or not prior art references teach different progenitor populations. As acknowledge by Applicant prior art teach a method of *in vitro* culturing and inducing differentiation of pluripotent stem cells. Clearly one skill in the art at the time the invention was made would know that pluripotent progenitor stem cells are the cells that can be induced to differentiate into various specialized types of cells of hematopoietic or non-hematopoietic lineage depending on the growth conditions and growth factors.

As has been discussed in the previous Office Action, WO' 629 teaches a new method for *in vitro* culture of progenitor cells, wherein that said cells are cultured under growth condition that promote differentiation, using three dimensional porous matrix having a unitary microstructure having a percent of open space of at least 75% and having a diameter of pores at mid-point on average of less than 150 μm (see page 5 lines 12 in particular). WO'629 teaches that porous solid matrix is a metal-coated wherein a metal is tantalum (see page 5, lines 10-25 in particular).). WO' 629 teaches porous solid matrix having seeded hematopoietic progenitor cells wherein said cells is impregnated with a gelatinous agent that occupies pores of the matrix

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(see pages 8-9 in particular). WO' 629 teaches that hematopoietic progenitor cells are obtained from blood product wherein blood product is unfractionated bone marrow (see pages 5 and 26 in particular). WO' 629 teaches that hematopoietic progenitor cells are Cd34⁺ or CD34⁻ or can be isolated from nonnucleated cells or enriched for cells having a common marker (see examples 1-4 in particular). WO' 629 teaches that hematopoietic progenitor cells are cultured in the presence of various growth factors that promote differentiation such as bFGF (see pages 6, 12, 15 and 16 in particular).

Though WO' 629 does not explicitly teach the growth conditions that promote differentiation to produce neuronal cells, WO' 629 does not limit the use of claimed method to induced differentiation only into hematopoietic cell lineage and excluded the use of different growth factors to promote hematopoietic progenitor cell differentiation into non-hematopoietic cell lineage.

US Patent '927 teaches a method for in vitro culturing progenitor cells to produce neuronal cells (see entire document, Abstract in particular). US Patent '927 teaches that although growth in the presence of only bFGF is sufficient to induce differentiation into neuronal cells, the presence of EGF in the differentiation medium is required for survival of cells (see columns 3, lines 1-15, column 6, lines 1-30 and column 21 in particular). US Patent '927 teaches a method for in vitro culturing progenitor cells to produce neuronal cells wherein growth differentiation medium comprises bFGF, EGF and NGF (see column 11, lines 1-10 Examples 10 and 25 in particular).

The Specification on page 11, lines 9-26 disclosed that at the time the invention was made a growth differentiation factors that promote differentiation into neuronal cells, such as bFGF, EGF or NGF were well known to those of ordinary skill in the art.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '927 and the known fact disclosed in the specification on page 11, lines 9-26 to those of WO' 629 to obtain a claimed method for in vitro culture of hematopoietic progenitor cells to produce differentiated cells of non-hematopoietic lineage, wherein said differentiated cells are neuronal cells and wherein differentiation conditions comprises bFGF and EGF.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because growth differentiation condition wherein said conditions comprising bFGF and EGF were well known in the art and used to produce neuronal cells as taught by the known fact disclosed on page 11 and US Patent '927. Said conditions can be used in the method for in vitro culturing progenitor cells to produce differentiated cells taught by WO' 629. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

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From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. No claim is allowed.

7. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

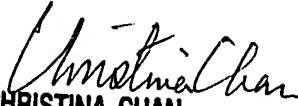
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 06, 2006


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